



# The Regulation of Health and Social Care Bill Consultation 2025



Closes: 03 October 2025 Opened: 22 August 2025

## **Overview**

# **Regulating Health and Social Care Activities**

Legislation, or laws, set out the fundamental rules and guidelines for how our health and social care system operates. Health and Social Care legislation is used to make sure that everyone receives safe, high quality medical and social care. Legislation is also used to set the standard of care, protect people's rights and ensure that the health and social care system is operating efficiently. A 'Bill' is a piece of primary legislation and once it has been approved by Tynwald it becomes an Act.

In this case, the Regulation of Health and Social Care Bill intends to replace the Regulation of Care Act 2013 (ROCA) to make sure that all health and social care service providers will now be regulated. To regulate means to make sure things are done properly, safely, or fairly. Regulation will continue to be carried out by the Department of Health and Social Care Registration and Inspection Team, with the option to commission external professionals with subject specific skills if and when required. This is important because it will help to make health and social care on the Island safer and help you to make the best choice possible about the care you want or need to receive.

The Department of Health and Social Care (DHSC) is seeking feedback on the draft Regulation of Health and Social Care Bill, which is due to be introduced in 2026.

The decision to pursue legislative reform comes from Recommendation 8 of the Sir Jonathan Michael <u>Independent Review of the Isle of Man Health and Social Care System</u>. The Bill's principles were established based on an identified need to expand the existing regulatory framework to health and other non-NHS sectors to protect the public and enhance the safety and well-being of service users.

A programme of early engagement with the local service providers and private businesses (known as 'stakeholders') who will be impacted, has already taken place from January to March 2025. The aim of the Bill is to make sure that all services delivering regulated health and social care activities must be subject to consistent and proportionate oversight to ensure safety, effectiveness, and the highest standards of care. This consultation is about





understanding your views on how the Bill will work in real life and how it affects you as either a service provider, professional or a service user.

Currently, the <u>DHSC's Registration and Inspection (R&I) Team</u> is responsible for regulating social care and non-NHS health care providers, including independent clinics. Under the new Bill this remit will expand to include all activities and treatments that may pose any level of risk to people's safety. This includes services such as physiotherapy, non-surgical cosmetic procedures (e.g. dermal fillers, tattoos, body piercers), general practice, dental surgeries, hospital and community services, and mental health care.

This approach focuses on regulating activities rather than just services and aligns with modern, risk-based regulatory models used in other jurisdictions (like England).

All regulated service providers will be subject to registration, monitoring and inspection. This will help ensure the public can have confidence in receiving compassionate, safe, quality and effective care.

This consultation invites feedback on the draft legal framework, its scope, and how it will work in practice. Your input will help shape the final version of the Bill before it is submitted to Tynwald.

For more information on the background of this Bill please visit the <u>ROHSC Bill webpage</u>, where the <u>Frequently Asked Questions</u> can also be found.

## Why your views matter

Health and care services impact all members of the Island's community. We want to make sure that the Regulation of Health and Social Care Bill is right for you and the people you care about. Providing your views will help us to ensure that the Bill, and the provision of services that it will underpin, works for you.

All feedback will be collated to identify themes, suggestions and any potential concerns to help inform and guide any future actions or developments for the Bill to enter the branches of Tynwald.

# Reasonable adjustments and alternative formats

The Department is committed to equal opportunities, and our aim is to make our documents easy to use and accessible to all.

We will take steps to accommodate any reasonable adjustments and provide such assistance as you may require enabling you to access or reply to this consultation.

If you would like to receive this document as a paper copy, in another format or need assistance with accessing or replying to this consultation, please email <a href="mailto:rohsc@gov.im">rohsc@gov.im</a>.

# **Sharing Your Feedback**

It is important to understand how this Bill will impact the wider health and social care system.

The proposed changes are significant, and we want to encourage all stakeholders, service providers and the public from across the health and social care system to share their views and participate in the consultation process.

The intention of this consultation is not to gather any personal, medical or health information. Any details of this nature provided within the consultation will be excluded and disposed of, under the relevant Data Protection quidelines.

#### Related

Regulation of Health and Social Care website





## **About you**

- In what capacity are you responding to this consultation? (required)
  - Member of the public
  - Service provider or professional
  - Service user
- 2. May we publish your response?

Please read our Privacy Policy for more details and your rights.

More Information

- Publish anonymously only your responses may be published on the hub
- Do not publish **nothing will** be published publicly on the hub (required)
  - o Yes, you may publish my response anonymously
  - o No, please do not publish my response

# **Consultation**

# **Question 1 – Service Provider Quality and Safety**

Regulation is fundamental for any modern health and social care system to protect the public.

The Health and Social Care system plays a vital role in supporting individuals, families, and our communities. To ensure these services are safe, effective, and trustworthy, it is important that they are regulated in a consistent and transparent manner.

Regulation helps to set clear standards for service providers, ensuring that everyone receives high-quality and safe services, regardless of who provides their care or service. It also helps to identify and address risks before harm occurs and supports continuous improvement.

The new Bill will make it easier for service providers to demonstrate the quality of their service and reassure service users that they are in safe hands. The application of risk based and proportionate regulation will reduce the frequency of inspections for services which are deemed to be lower risk.

#### The new Bill will help to support the continuous improvement of service providers by:

- Finding new and better ways to keep improving services
- Sharing what works well so others can use it too
- Using a variety of ways to gather feedback from people who use the service
- Using data and findings to help make smarter decisions to improve services
- Team up with other services to provide more joined-up and coordinated care
- Continually checking how well treatment and care are working for people

# In what specific ways do you believe regulation will have the most impact on the health and social care system?

- Helping people understand what to expect from a service
- Making sure service providers take responsibility for what they do
- Helping people trust a service
- Safeguarding or protecting those who need the most help
- Listening to and learning from the people who use the service
- o Ensuring inspection results are open and easy to understand
- o Establishing up-to-date rules and standards to ensure best practice





# **Question 2 – Registration Prioritisation**

The current standards for health and social care service providers on the Isle of Man are set out in the <u>Regulation of Care Act (ROCA) 2013</u> and its associated <u>Regulations</u>.

The Regulation and Inspections (R&I) Team sits in the DHSC and is responsible for the registration, inspection, and monitoring of a range of service providers. This ranges from care homes to nurseries and childminders, independent clinics offering treatments involving the use of specific types of lasers and medical agencies offering services by medical practitioners outside of the NHS.

Other services such as NHS health care provided by Manx Care, private health services, various cosmetic services, tattooist, and body piercers are not regulated by the DHSC Registration and Inspection Team. The <u>Sir Jonathan Michael's independent review</u> highlighted that the new Bill should expand regulation to cover all health and social care activities on the island.

Tattooists are currently regulated by the by the Department of Environment, Food and Agriculture (<u>DEFA</u>) through its <u>Environmental Health Unit</u>, although will now be captured by the new Bill.

#### A service provider

This is the name given to an organisation that provides a service. This could mean a General Practice (GP) Surgery, Childminder, Tattooist, Midwifery or Physiotherapy that provides a health and/or social care regulated activity or activities.

Examples of service provider can be:

- An individual sole trader
- A partnership
- A body corporate

#### A regulated activity

This is an activity connected with the provision of health or social care at a registered service provider location.

#### Health care includes:

- All forms of health care provided for individuals relating to physical or mental health
- Non-surgical cosmetic procedures.
- Complementary and alternative therapies.

#### Social care includes:

 All forms of personal care and practical assistance provided for individuals who by reason of age, illness, disability, pregnancy, childbirth, dependence on alcohol or drugs, or any other applicable circumstances need help.

A service provider may perform a single activity or a combination of activities.

Examples of a regulated activity can be:

- A surgical procedure
- Treatment of disease, disorder, or injury
- Personal care
- Non-surgical cosmetic procedures
- Services in slimming clinics
- Maternity and midwifery
- Care and accommodation for children

Due to the number of services that will become regulated under the new Bill, the intention is to take a phased approach to the registration of all services. It is estimated that this will take between 2 and 4 years. We want to know which are the most important services for you so we can decide the services which should apply for registration (and be regulated) first.





In your opinion, what order should the health and social care service providers apply for registration? (place answers in order of priority)

- o Primary Care (e.g. NHS General Practitioners, Opticians)
- o Community Services (e.g. Wellbeing Hubs, Health Visiting and School Nursing, Vaccine service, Community Dental Service)
- Acute Care (Hospital based services e.g. Day Procedure Suite, Out-patients, Manx Emergency Doctors Service, Minor Injuries Unit, Ophthalmology)
- o Independent Medical Agencies and Clinics (Private General Practice Doctors, cosmetic procedures (nonsurgical), tattooist, body piercers, therapists)

Are there any factors you believe should guide the order in which service providers are registered? (place answers in order of priority)

- Vulnerability of Service Users (services that support vulnerable people e.g. children, older adults, or individuals with disabilities)
- Volume and Reach of Services (services supporting a wider range of people e.g. general practice, dental surgeries)
- Public Confidence and Transparency (services where public trust is essential to build confidence e.g. the hospital)
- o Risk of Harm (services where failure or inadequate quality could result in significant harm to individuals).
- o Emerging Services (new service models that may not yet be well understood or regulated)

## Question 3 – Risk-Based Inspection Methodology

The R&I Team will conduct inspections of service providers on a risk-based schedule relating to safety and quality factors. This means that service providers will not always require an annual inspection and that some services will be regulated more often than others.

The Department is proposing there should be a minimum time limit between inspections for the lowest risk services.

Other services that have higher associated risks with the type of regulated activities being offered may have more frequent inspections. Risk-based regulation enables the Department to concentrate its support and resources on services that have been identified to be in the greatest need of improvement.

Services will be monitored between inspections, using various methods including reviewing data notifications around areas such as behavioural well-being, staffing levels, medication errors or estate issues, and listening to people's experiences. This methodology aims to ensure resources are targeted in accordance with risk.

# What do you think is the most effective way to schedule the monitoring and inspection of health and social care services?

(tick the appropriate option)

- o Prioritise inspections based on the assessed risk level of service providers
- A combination of risk-based and time-based scheduling depending on the type, size and compliance history of a service provider
- o A flexible approach based on emerging concerns, complaints or changes in service provision
- o Analysis of service provider self-assessments to help determine the inspection frequency
- A blended model incorporating each the methods to balance adaptability, support continuous improvement and ensure that regulatory oversight remains proportionate and effective





In your opinion how often, at a minimum, should services considered to be minimal risk be inspected? (select the appropriate option)

- Every 3-5 years
- o Every 2-4 years
- Other (please specify)

Please explain your vie	w:		

# **Question 4 – Subject Matter Expert Regulation Support**

To support the risk-based inspection regime, the R&I Team will collaborate with Subject Matter Experts.

Subject Matter Experts bring a wealth of experience and expertise, which is essential for safe and effective regulation. Their insights help identify opportunities and solutions, to ensure services evolve to meet ever-changing needs. SMEs' expertise in navigating complex regulations allows them to address challenges and make informed decisions that enhance patient outcomes and service delivery.

The Department has considered all aspects of the R&I Team working with Subject Matter Experts who will bring specific expertise around:

- Accurate and technically sound comprehension of regulation, reducing uncertainty and unintended risks
- Operational context providing insight to identify where reforms or policy changes are needed most
- Experienced with legislation to ensure reforms are feasible and meet stakeholder needs
- Informed decision-making around evidence-based data and findings to support recommendations
- Practical insight and foresight to enhance governance and compliance
- Mitigation of risks and early identification of potential issues to enable effective responses
- Increased credibility to the reform process, which can boost public confidence and trust

# Are there any areas of the health and social care system you think may benefit from involvement with a subject matter expert?

- o Primary Care (e.g. NHS General Practitioners, Opticians, Dentists)
- Community Services (e.g. Wellbeing Hubs, Health Visiting and School Nursing, Vaccine service, Community Dental Service)
- Acute Care (Hospital based services e.g. Day Procedure Suite, Out-patients, Manx Emergency Doctors Service, Minor Injuries Unit, Ophthalmology)
- Independent Medical Agencies and Clinics (Private General Practice Doctors, cosmetic procedures (nonsurgical), tattooist, body piercers, therapists)





Are there any add covered above?	re there any additional areas of expertise you believe could be included that have not been overed above?					een	

# **Question 5 – Non-Surgical Cosmetic and Aesthetic Services**

Non-surgical cosmetic and aesthetic services are currently unregulated by the R&I Team on the Isle of Man. However, the new Bill will introduce regulation for a range of procedures. This will include things like cosmetic dermal fillers; the application of substances capable of penetrating the epidermis (skin); the placement of threads; the insertion of needles into the skin (including tattooing); and the use of light, electricity, heat or cold-based therapies.

The Bill aims to ensure these procedures are delivered safely, ethically and professionally. It proposes safeguards to the legal minimum age of 18 for receiving cosmetic injections for non-medical purposes, (Section 71 Offence of administering certain substances to a child) even with parental consent. Exceptions would only apply when a treatment is medically necessary and recommended by a qualified medical practitioner. This does not affect existing age for consent to medically necessary care (16).

Currently, individuals aged 16 and over can consent to health and social care services without parental approval. This right would remain unchanged for general care, however, would change to 18 with the specified cosmetic procedures under the new legislation.

These changes would align the Isle of Man with legislation in other jurisdictions, such as England's Botulinum Toxin and Cosmetic Fillers (Children) Act 2021. Providers would be required to meet safety and quality standards, with non-compliance to be subject to enforcement action.

Which factors are most important to ensure service providers of non-surgical cosmetic procedures (e.g. aesthetic filler injections for appearance-related reasons) follow best practice to minimise harm?

(place answers in order of priority)

- Appropriate medical or aesthetic qualifications and ongoing training to stay up to date with new techniques
- o Practitioners required to operate in clean, hygienic, and properly equipped environments
- o Practitioners supply clear information about a procedure, risks, side effects, and costs
- Only approved and regulated products should be used, stored and managed correctly
- Secure systems in place to monitor outcomes, report complications, aftercare and emergency response
- o Adequate professional indemnity insurance and mechanisms for complaints and accountability
- o Truthful advertising, without targeting vulnerable groups (e.g. young people)

To reinforce the age restrictions, it may be necessary for residents to provide identification for nonsurgical cosmetic procedures (e.g. aesthetic filler injections for appearance-related reasons).





Which of the following Identification methods would be acceptable: (select all that apply)

- Passport
- Driving Licence
- o Digital Connect ID
- o Birth Certificate
- Proof of Age Card

# **Question 6 – Raising the Age of Childcare**

The R&I Team currently requires child day-care service providers caring for children under 8 years old to register and pay an annual fee.

The new Bill proposes extending these requirements to include providers caring for children up to the age of 12 (Schedule 1, Section 8 Regulated Activity 16). This change aims to enhance child safeguarding by broadening regulatory oversight and ensuring more children benefit from structured, supervised care environments.

This proposal aligns with best practice standards across the different jurisdictions, where the age threshold has already been raised to 12 and if not higher in some circumstances. It reflects the evolving needs of working families and acknowledges that children up to this age must continue to benefit from safe and supportive day care settings.

Under the existing Act (ROCA), the R&I Team regulate childminders, child day care services which includes nurseries and playgroups. This would continue under the new Bill.

Certain services for children such as after-school activities, holiday clubs, sport, activity and youth clubs could also be subject to regulation, to ensure the safety and wellbeing of participants.

The Department has considered the mitigation of any potential concerns or safety risk. Do you ha any additional feedback or concerns that you would like to provide?				
Are there any addi	itional services you	think could be in	cluded in the new l	Bill?





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service	es (such as ch	hildminders, n	urseries and y	outh clubs) tha	t you would like	e to share?	

# **Question 7 – Registration and Annual Fees**

Under the Regulation of Care Act 2013, regulated service providers are required to register with the Department and pay a fixed registration and annual fee (Subdivision 5 – FEES, Section 62). More information about the current fee structure is available below.

Fees = for all Care Services (Payable to Isle of Man Government)

Care services Category	Care Service	Size of Care Service	Registration fee	Managers fee	Amendment fee	Annual fee
Childminding	Childminders		£80	N/A	Minor = £30 Another = £80	£55
Establishments – Day Care	Child Day care Centre Adult Day Centre Mental Health Day Centre	Small = fewer than 10 places Medium = 10 or more but fewer than 21 places Large = another care service	£320 £350 £400	£425	Minor = £55 Another = £105	£105 £160 £210
Agencies & Independent Clinics	Adult Placement Agency Child Care Agency Domiciliary Care Agency Fostering Agency Independent Medical Agency Voluntary Adoption Agency Independent Clinic – Beauty Clinics	Small = fewer than 3 persons employed on full time basis Medium = 3 or more but fewer than 16 persons employed on full time basis Large = another care service	£1,060 £1,165 £1,270	£425	Minor = £55 Another = £105	£320 £475 £635
Establishments – Boarding School	Boarding Schools	Small = fewer than 40 places  Medium = 40 or more but fewer than 100 places  Large = another care service	N/A	N/A	N/A	£320 £475 £635
Establishments – Care Homes	Adult Care Home  Children's Home  Child – Secure Accommodation Independent Hospital  Offender Accommodation Service	Small = fewer than 20 places  Medium = 20 or more but fewer than 41 places  Large = another care service	£1,480 £1,690 £1,905	£425	Minor = £105 Another=£690	Small=£55 x no. of registered places  Medium=£60 x no. of registered places  Large=£65 x no. of registered
	Residential Family Centre		30	63		places

Family Centre

Reference : Regulation of Care (Registration) Regulations 2013 (Schedule 5 and Schedule 6)
Regulation of Care (Care Services) Regulations 2013 (Schedule 1)

The new Bill will introduce a sliding fee scale for new service providers to register, and annual fees to remain registered. The scale could be based on several factors such as the size of a business, the number of full-time employed staff, the financial statement and/or the number of people using a service.

These factors should be considered when designing a sliding fee scale for service providers.





This approach aims to make the fee structure more equitable, helping to reduce the financial burden on smaller service providers while ensuring that larger providers contribute proportionately. For example, under the existing Act, a Childminder pays an annual fee of £55, a medium size Independent Clinic (Beauty Clinic) pays £475 and a large Adult Care Home with 45 places would pay £2925.

While the principle of the sliding fee scale remains the same, the fees themselves may be subject to change.

Regulation fees are essential to support the DHSC Registration and Inspection Team to ensure safe, high-quality health and social care services across the island. Collecting fees proportionate to a service provider size and activity, ensures the cost of regulation is fairly distributed, service providers are accountable for the quality of care being delivered and the system remains financially sustainable and responsive to growth.

Do you support the introduction of a sliding fee scale for service providers, where fees are based on differing factors to ensure fairness and transparency?

- Yes, a sliding fee scale should be introduced to ensure the fees are proportionate and equitable across distinct types of service providers
- o No, a fixed fee structure should be introduced based on a service type or registered activity for simplicity

Please explain your view:			

Which of the following factors do you believe should be considered to ensure the sliding fee scale is fair, transparent, and proportionate?

- Number of staff employed at a location (larger organisations with more staff may have greater capacity to contribute higher fees)
- Annual revenue or financial position (fees could be scaled based on the provider's financial statements or profit margins to ensure affordability and fairness)
- Number of service users (providers serving more clients may be charged more, reflecting their scale of operation)
- Number of regulated activities (larger organisations may offer a wider range of services and therefore more regulated activities)
- Duration of operation (newer providers might receive temporary fee reductions to support early-stage development)
- Frequency or volume of service delivery (providers offering services more frequently or at higher volumes may be subject to different fee levels)
- Organisation type (differentiating between private businesses, charities, and community-based organisations)





# **Question 8 – Regulation Rating System**

The R&I Team, under the Regulation of Care Act 2013, currently undertake detailed inspections of social care and a handful of non-NHS service providers, such as independent clinics and medical agencies, including private doctors. These reports are made available on the Department website, however, they do not include a rating system to describe the service. This is different to other regulators, for example, who may use 'outstanding', 'good', 'requires improvement' and 'inadequate'.

It is important to note that regulators in England are reviewing how ratings are calculated. The aim is to enhance clarity, transparency and build a more robust and reliable system. However, receiving a poor rating can have consequences, including the loss of clients and service users, and damage to reputation. We want to understand what you need from a rating system.

Do you think introducing a clear and accessible rating system for inspection reports would help the public better understand the safety, effectiveness and quality of health and social care service providers?

- Yes, a rating system will be helpful in making inspection outcomes more transparent and easier for the public to understand
- o No, a detailed report without a summary rating is sufficient

Please explain your view:			

If a rating system was introduced for inspection reports, how would you prefer the ratings to be presented to make them clear, meaningful and easy to understand? (select the appropriate option)

- Descriptive categories (example: outstanding, good, requires improvement and inadequate).
- Star ratings (example:  $\star \star \star \star \star \star \div$  4 out of 5 stars)
- o Colour-coded levels (example: green, amber, and red)
- Numerical scores (example: 5/10 or 9/10)

If a rating system is introduced, where should this information be made available to ensure it is accessible and useful to the public?

- o On the service provider's website
- On the DHSC R&I website
- In printed materials available at service provider locations
- Through social media
- Via the service providers app (if applicable)





# **Question 9 – Regulation Framework for Service Providers**

The information below is only relevant to service providers. If you're responding as a service user or member of the public, please skip this section.

As part of the implementation of the Regulation of Health and Social Care Bill, we are keen to understand the experiences and concerns of service providers.

We recognise that any new system can bring both opportunities and challenges. Whether you're adapting existing practices, navigating new compliance requirements, or seeking clarity on your responsibilities, your feedback is essential to shaping a supportive and effective regulatory framework.

As a service provider, what concerns or challenges do you anticipate in meeting the requirements of the Regulation of Health and Social Care Bill 2026?

Please consider aspects such as registration, compliance, inspections, training, communication, or any other area where you feel additional support or clarification may be needed. (tick all that apply)

- Understanding the scope of regulated activities
- Navigating the registration process
- Meeting compliance and inspection standards
- Accessing training and guidance materials
- o Communicating effectively with the regulatory body
- o Managing the cost or administrative burden of compliance
- o Ensuring staff are adequately prepared and informed

rthere are other concerns or chanenges you anticipate that we haven t listed, please enter the elow:	<i>em</i>





# **Question 10 – Stakeholder Feedback**

Thank you for taking your time to answer this consultation regarding the new Regulation of Health and Social Care Bill.

We recognise that stakeholder feedback plays a vital role in shaping effective legislation, regulation and policy.

To help us better understand your preferences, we would like to know your preferred method or platform for providing feedback on matters related to service providers, legislation, regulation, or policy development.

(tick all that apply)

- o Written feedback form
- Email
- Social media
- App (service provider)
- Telephone
- Website feedback form
- Face-to-face
- o Anonymously

If you have any questions or would like to provide any further feedback about this Bill, email the ROHSC Team at <a href="mailto:rohsc@gov.im">rohsc@gov.im</a>.

Additional Comments
Do you have any comments, questions or concerns regarding the new Bill that you would like to share?

#### **Contact**

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